

WHAT IS CLAIMED IS:

1                   1.       A method for eliciting an immune response in a subject comprising  
2     administering an immunogenically effective amount of a peptide or protein antigen  
3     comprising one or more T cell epitope(s) coordinately with a non-viral vector comprising  
4     a polynucleotide encoding a T cell co-stimulatory molecule.

1                   2.       The method of claim 1, wherein the peptide or protein antigen  
2     comprises a T cell epitope of a tumor antigen or viral antigen.

1                   3.       The method of claim 2, wherein the tumor antigen is selected from  
2     p53, *ras*, *rb*, *mcc*, *apc*, *dcc*, *nfl*; VHL; MEN1, MEN2, MLM, Her-2neu, CEA, PSA;  
3     Muc1, Gp100, tyrosinase, or MART1.

1                   4.       The method of claim 3, wherein the tumor antigen is selected from  
2     a mutant or normal p53 or *ras* protein.

1                   5.       The method of claim 4, wherein the peptide antigen comprises a  
2     sequence of at least nine amino acids spanning a mutation in p53 or *ras*.

1                   6.       A method for eliciting an immune response in a subject comprising  
2     administering an immunogenically effective amount of a protein antigen comprising at  
3     least one T cell epitope coordinately with a non-viral vector comprising a polynucleotide  
4     encoding a T cell co-stimulatory molecule.

1                   7.       The method of claim 2, wherein the viral antigen is selected from a  
2     human immunodeficiency virus (HIV), hepatitis B virus (HBV), hepatitis C virus (HCV),  
3     herpes simplex virus (HSV) or human papilloma virus (HPV) antigen.

1                   8.       The method of claim 7, wherein the peptide antigen comprises at  
2     least nine contiguous amino acids of a HPV antigenic protein.

1                   9.       The method of claim 7, wherein the peptide antigen comprises at  
2     least nine contiguous amino acids of a HIV antigenic protein.

1                   10.      The method of claim 7, wherein the peptide antigen comprises at  
2     least nine contiguous amino acids of a HBV or HCV antigenic protein.

1 11. The method of claim 1, wherein the co-stimulatory molecule is  
2 selected from B7-1, B7-2, B7-3, B7-H, ICAM1, ICAM2, ICAM3, LFA1, LFA2 or LFA3.

1 12. The method of claim 11, wherein the co-stimulatory molecule is  
2 B7-1.

1 13. The method of claim 1, wherein the peptide antigen and non-viral  
2 vector encoding one or more T cell co-stimulatory molecules are administered to the  
3 subject simultaneously as a mixture in a pharmaceutically acceptable carrier or diluent.

1 14. The method of claim 1, wherein the peptide antigen and non-viral  
2 vector encoding the T cell co-stimulatory molecule are administered separately to the  
3 subject in a sequential vaccination protocol.

1 15. The method of claim 1, wherein the peptide antigen and non-viral  
2 vector encoding the T cell co-stimulatory molecule are administered to proximal target  
3 sites selected from the same, or closely-adjacent, intradermal, subcutaneous, mucosal or  
4 intratumoral sites.

1 16. The method of claim 1, wherein the non-viral vector is selected  
2 from a RNA or DNA vector.

1 17. The method of claim 1, wherein the non-viral vector comprises a  
2 naked DNA vector having the polynucleotide encoding the co-stimulatory molecule  
3 operably linked to regulatory elements necessary for expression of the co-stimulatory  
4 molecule in eukaryotic cells.

1 18. An immunogenic composition comprising an immunogenically  
2 effective amount of a peptide or protein antigen comprising a T cell epitope, and a non-  
3 viral vector comprising a polynucleotide that encodes a T cell co-stimulatory molecule  
4 operably linked to regulatory elements necessary for expression of the co-stimulatory  
5 molecule in eukaryotic cells, formulated in a pharmaceutically acceptable carrier or  
6 diluent.

1 19. The immunogenic composition of claim 18, wherein the peptide  
2 antigen comprises a T cell epitope of a tumor antigen or viral antigen.

1 20. The immunogenic composition of claim 19, wherein the tumor  
2 antigen is selected from p53, *ras*, *rb*, *mcc*, *apc*, *dcc*, *nfl*; VHL; MEN1, MEN2, MLM,  
3 Her-2neu, CEA, PSA; Muc1, Gp100, tyrosinase, or MART1.

1 21. The immunogenic composition of claim 20, wherein the peptide  
2 antigen comprises a sequence of at least nine amino acids spanning a mutation in p53 or  
3 *ras*.

1 22. The immunogenic composition of claim 18, wherein a protein  
2 antigen is administered as a purified protein or a tumor lysate component of a vaccine  
3 formulation.

1 23. The immunogenic composition of claim 19, wherein the viral  
2 antigen is selected from an antigenic protein of human immunodeficiency virus (HIV),  
3 hepatitis B virus (HBV), hepatitis C virus (HCV); herpes simplex virus (HSV), or human  
4 papilloma virus (HPV) antigen.

1 24. The immunogenic composition of claim 23, wherein the peptide  
2 antigen comprises at least nine contiguous amino acids of a HPV E6 or E7 protein.

1 25. The immunogenic composition of claim 23, wherein the peptide  
2 antigen comprises at least nine contiguous amino acids of a HIV antigenic protein.

1 26. The immunogenic composition of claim 23, wherein the peptide  
2 antigen comprises at least nine contiguous amino acids of a HBV antigenic protein.

1 27. The immunogenic composition of claim 18, wherein the co-  
2 stimulatory molecule is selected from B7-1, B7-2, B7-3, B7-H, ICAM1, ICAM2, ICAM3,  
3 LFA1, LFA2 or LFA3.

1 28. The immunogenic composition of claim 27, wherein the co-  
2 stimulatory molecule is B7-1.

1 29. The immunogenic composition of claim 18, wherein the non-viral  
2 vector is selected from a RNA or DNA vector.

1                    30.    The immunogenic composition of claim 29, wherein the non-viral  
2    vector comprises a naked DNA vector having the polynucleotide encoding the co-  
3    stimulatory molecule operably linked to regulatory elements necessary for expression of  
4    the co-stimulatory molecule in eukaryotic cells.

1                    31.    The immunogenic composition of claim 18, wherein the peptide  
2    antigen comprises a cytotoxic T cell (CTL) epitope.